K061805

1) 510K Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K061805

DEC - 6 2006

a) Applicant Name and Address

Applicant:	Diagnostica Stago, Inc.
Address:	5 Century Drive
	Parsippany, NJ 07054
Contact Person:	Bob Wallish
Phone #:	800-222-2624, x 2044
Fax #:	973-631-1618
E-mail:	Bob.Wallish@stago-us.com
Date of Preparation:	11/29/06

b) Device Name

Trade Name:	STA® Staclot® dRVVT Screen and Confirm
Common Name:	Dilut Russsell's Viper Venom Kits
Classification Name:	RUSSELL VIPER VENOM REAGENT (21 cfr 864.8950, Product Code ~~GFO~~) GIR

c) Predicate Device

LAC Screen and Confirm manufactured by Instrumentation Laboratories (K990302).

d) Intended Use/Device Description

The STA®-Staclot® dRVV Screen and STA®-Staclot® dRVV Confirm kits are intended for the detection of lupus anticoagulants (LA) in plasma by the dilute Russell's viper venom method (1) performed with analyzers of the STA® line suitable to these reagents.

e) Technological Characteristic Summary

The in vitro diagnostic device presented in this 510K submission, STA® -Staclot® dRVV Screen and STA® -Staclot® dRVV Confirm, is substantially equivalent to the IL Test LAC Screen and Confirm manufactured by Instrumentation Laboratories. A comparison of the two kits is summarized in the following table.

Ninety plasmas obtained from patients with various clinical pathologies were tested with both kits at two sites. The percent agreement was 92%.

Applicable Technology	STA® - Staclot® dRVV Screen and Confirm	LAC Screen and LAC Confirm
Intended Use	The STA®-Staclot® dRVV Screen and STA®-Staclot® dRVV Confirm kits are intended for the detection of lupus anticoagulants (LA) in plasma by the dilute Russell's viper venom method performed with analyzers of the STA® line suitable to these reagents.	Diluted Russell's Viper Venom Test (DRVVT) reagents for the detection of lupus anticoagulants (a type of phospholipid interfering antibody) in human citrated plasma on the IL Coagulation systems. **LAC Screen**: Simplified DRVV reagent to screen for the presence of Lupus Anticoagulants **LAC Confirm**: Phospholipid rich DRVV reagent to confirm the presence of Lupus Anticoagulants.
Reagent Composition	Russell's viper venom, phospholipids, calcium and heparin inhibitor.	Russell's viper venom, phospholipids, calcium, heparin inhibitor, buffers, stabilizers, dyes and preservative.
Reagent Stability	*Intact vials at 2-8 °C*: until expiration *Reconstituted on analyzer (15-20°C)*: 72 hours	*Intact vials at 2-8 °C*: until expiration *Reconstituted:* 2-8 °C:48 hr 15-25 °C: 24 hr -20 °C:1 mo
Test Sample	Citrated plasma	Citrated plasma
Expected Values	Normalized Ratio: </= 1.20	Normalized LAC Ratio: 0.8-1.2
Intra-Assay Reproducibility	Normal: CV%=0.5 LA Positive: CV%= 0.4	Normal: CV%=1.16 LA Positive CV%= 0.84
Inter-Assay Reproducibility	Normal: CV%=2.2 LA Positive : CV%= 3.0	Normal: CV%=1.70 LA Positive: CV%= 3.02

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Laura A. Worfolk, Ph.D.
Acting Director of Quality Control and Regulatory Affairs
Diagnostica Stago, Inc
5 Century Drive
Parsippany, NJ 07054

DEC - 6 2006

Re: k061805
Trade/Device Name: STA® STACLOT® dRVV Screen and Confirm
Regulation Number: 21 CFR § 864.8950
Regulation Name: Russel viper venom reagent
Regulatory Class: I
Product Code: GIR
Dated: October 25, 2006
Received: October 26, 2006

Dear Dr. Worfolk:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

Sincerely yours,

Robert L. Becker, Jr., MD, Ph.D
Director
Division of Immunology and Hematology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): _____

Device Name: STA®-STACLOT® dRVV Screen and

STA®-STACLOT® dRVV Confirm

Indications for Use:

The STA®-Staclot® dRVV Screen and STA®-Staclot® dRVV Confirm kits are intended for the detection of lupus anticoagulants (LA) in plasma by the dilute Russell's viper venom method (1) performed with analyzers of the STA® line suitable to these reagents.

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

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Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)